



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/664,314

09/17/2003

Glen E. Southard

1888-SPL

4173

26085

7590

03/21/2007

THE JOHNS HOPKINS UNIVERSITY APPLIED PHYSICS LABORA

OFFICE OF PATENT COUNSEL

11100 JOHNS HOPKINS ROAD

MAIL STOP 7-156

LAUREL, MD 20723-6099

EXAMINER

WALLENHORST, MAUREEN

ART UNIT

PAPER NUMBER

1743

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
--	-----------	---------------

3 MONTHS

03/21/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/664,314	Applicant(s) SOUTHARD, GLEN E.	
	Examiner Maureen M. Wallenhorst	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-70 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-10, 12-24, 32-39, 41 and 60-70 is/are allowed.
- 6) ☒ Claim(s) 11, 25-31, 40 and 42-59 is/are rejected.
- 7) ☒ Claim(s) 45-48, 50, 51, 53 and 57-59 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Art Unit: 1743

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because of the inclusion of legal phraseology such as "comprising". Correction is required. See MPEP § 608.01(b).
3. Claims 11, 25-31, 40, 42-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On lines 2-3 of claim 11, the phrase "we should claim Fe(II) too, since it would be the metal of choice for histamine" is indefinite since it does not make proper sense in the claim. Claim 11 is directed to the type of biogenic amine detected by the molecularly imprinted polymer of independent claim 7.

Claim 25 is indefinite since the preamble of the claim recites a sensor for detecting the presence of a biogenic **amine** in a fluid. However, the last two lines of claim 25 recite that the polymer undergoes a detectable color change upon exposure to a biogenic **diamine**. It is not clear whether the sensor detects a biogenic **amine** or **diamine**. See this same problem with the phrase "biogenic diamine" on line 2 of claims 29 and 40.

On line 1 of claim 42, the phrase "The method of Claim 34 25" does not make proper sense.

On line 6 of claim 43, the phrase “the filter” lacks antecedent basis since part b) of claim 43 recites “a filtration unit”, not a filter.

In claim 46, the phrase “the aromatic groups to which R1 and R2, R3 and R4, R5 and R6 and R7 and R8 can form” lacks antecedent basis since claim 46 depends from independent claim 43, not claim 45 that positively recites the structure of the macrocyclic transition metal complex. Claim 46 should be amended to depend from claim 45. See this same problem in claims 47-48.

On line 1 of claim 50, the phrase “the macrocyclic transition metal complex” lacks antecedent basis since claim 50 depends from independent claim 43, and claim 43 does not positively recite a macrocyclic transition metal complex. Claim 50 should depend from claim 45.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 43, 49, 52, 54 and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Kalivretenos (US 2003/0104609).

Kalivretenos teaches of an amine detection method and devices for performing the method. One example taught by Kalivretenos where it is useful to detect biogenic amines is for detecting food spoilage in fish or meat. Kalivretenos teaches that as raw fish and meat spoil due to improper handling or age, chemically reactive amines are produced in high concentrations. These chemically reactive amines include histamine, putrescine and cadaverine. See paragraphs

Art Unit: 1743

0039 and 0072 in Kalivretenos. Kalivretenos teaches of a compound bound to a polymer that is used to detect biogenic amines in fluids. The compound is 1-hydroxybenzotriazole-6-carboxylic acid. This polymer-bound compound can be used in a disposable sensor device for the detection of spoilage in packaged fish and meats. The polymer-bound compound contains a dye as an activated ester or sulfonate ester. When amines free in a sample react with the immobilized 1-hydroxybenzotriazole-6-carboxylic acid, the dye is released, causing a color change to occur in the sensor. The intensity of the color is proportional to the total amine concentration in the sample. Kalivretenos teaches that one embodiment of a sensor for detecting amines in samples such as food products includes a flow-through device such as a syringe having an inlet traversed by a fluid, a filtration unit in the form of a frit mounted in the syringe downstream from the inlet, and a biogenic amine detecting compound (i.e. polymer-bound 1-hydroxybenzotriazole-6-carboxylic acid) located in the syringe downstream of the filter frit material that undergoes a color change upon exposure to a biogenic amine. See Figure 5c and paragraph nos. 0043-0046 in Kalivretenos. Preferably, the 1-hydroxybenzotriazole-6-carboxylic acid is linked to a solid support such as silica gel or cellulose in the syringe-device. Kalivretenos also teaches that devices for detecting biogenic amines in food samples as an indication of food spoilage can be incorporated into a diagnostic kit. See paragraph 0077 in Kalivretenos.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 44 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kalivretenos. For a teaching of Kalivretenos, see previous paragraphs in this Office action.

Kalivretenos fails to teach the pore size of the filter frit material in the syringe-like device for detecting biogenic amines in a fluid sample. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to adjust the pore size of the filter frit material in the syringe-like device taught by Kalivretenos since the pore size of a filter is a result effective parameter that can be experimentally adjusted in order to optimize the separation of impurities in a sample that may cross-react with the amine-detecting compound disclosed by Kalivretenos. Kalivretenos also fails to teach of analyzing a body fluid for the presence of biogenic amines therein. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to use the device taught by Kalivretenos to detect biogenic amines in a body fluid since Kalivretenos discloses that biogenic amines are present in living cells (see paragraph no. 0039 in Kalivretenos), and therefore, a body fluid would contain biogenic amines that have been secreted from cells in the fluid.

9. Claims 45-48, 50-51, 53 and 57-59 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the

Art Unit: 1743

limitations of the base claim and any intervening claims since none of the prior art of record teaches or fairly suggests a device and method for detecting a biogenic amine in a fluid sample by reacting the fluid sample with a macrocyclic transition metal complex comprising the chemical structure as set forth in claim 45, wherein the different R groups on the structure taken together with the adjacent carbon atoms to which they are bonded are joined together to form the same or different group selected from an aromatic or a cyclic group, with at least one of the aromatic or cyclic groups possessing one or more polymerizable moieties that undergo a colorimetric change in the presence of a biogenic amine.

10. Claims 1-10, 12-24, 32-39, 41 and 60-70 are allowable as is over the prior art of record for the same reasons as given above.
11. Claims 25 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action for the same reasons as given above.
12. Claims 11, 26-31, 40 and 42 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims for the same reasons as given above.
13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Please make note of: Kelly et al (US Patent nos. 6,593,142 and 6,924,147), which represent the closest prior art to the instant claims since these patents teach of polymeric food spoilage sensors for detecting biogenic amines such as cadaverine in food samples having a polyazamacrocyclic transition metal complex therein for selectively binding to amines. These transition metal complexes, however, do not have R groups therein that taken together with the

Art Unit: 1743

adjacent carbon atoms to which they are bonded, are joined together to form the same or different group selected from an aromatic or a cyclic group, with at least one of the aromatic or cyclic groups possessing one or more polymerizable moieties that undergo a colorimetric change in the presence of a biogenic amine.

Also, please make note of: Richman who teaches of macrocyclic polyamines; Wallach, Miller et al, Veretto et al and Lawdermilt who teach of different spoilage food indicators.

The references included with the Information Disclosure Statement (IDS) filed on February 23, 2004 are cited and made of record on the PTO-892 form attached to this Office action since there was no 1449 form attached to the IDS. Copies of these references are not included with this Office action since the copies were already submitted by Applicant with the IDS. The references on the IDS include: WO 01/77667, WO 01/77672, WO 01/77664, JP360188096A, JP358141798A, JP55141199, Suslick et al, Blixt et al and Kang et al.

Art Unit: 1743

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

March 13, 2007

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP ~~100~~ 1700